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NIXON & VANDERHYE, PC			SPIELER, SHAHZAD	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,908	Applicant(s) WOLLWAGE, PETER
	Examiner SHAHRZAD SPIELER	Art Unit 1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 18-29 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement (PTO/SB/08) _____
 Paper No(s)/Mail Date 2 sheets.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claim Objections

Claim 18 is objected to because of the following informalities: In claim 18, "valve" should read --"value"-- Appropriate correction is required.

Claim 23 is objected to because of the following informalities: in claim 23, "tensed" should read --"tenside"--. Appropriate correction is required.

Claim Rejections - 35 USC § 101 ("Use")

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18-29 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did ‘little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.’)

Mere indistinct terms (such as “aromatic substance adjuvants” used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See Univ. of Calif. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful aromatic substance adjuvants, generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18, the term “aromatic substance adjuvants” “whenever appropriate” and the meaning of the phrase “certain quantity” is unclear. Claim 18 is incomplete insofar as it fails to identify the variables “C1¹” and C1⁰. Claim 18 also states “the claimed range” which lacks antecedent basis.

Claim 18, the term “preferably” and “more preferably in claim 18 is a relative term which renders the claim indefinite. The term ” preferably” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is impossible to determine if the preferred embodiments are required Claim 18; no guidance is provided for determining the preferred embodiments.

Claim 18, the phrase "and the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "and the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim 19 recites an improper “range within a range” due to its use of the term “especially.”

Claim 20 also recites improper “range within a range” language. There are two occurrences of “for example”; one occurrence of “such as” in claim 20.

Claim 20 recites the term “effervescent salts-effervescents” in parentheses; it is unclear if this term is drawn to the claimed invention.

Claim 22, states the terms “e.g.”, “preferably”, and “such as”, these terms are unclear. It is not clear what is intended by the term “carbon acid.” These terms, could in theory, refer to inorganic acids, e.g. carbonic acid; could refer to organic acids, etc., such that the meaning of the term is entirely unclear.

Claim 22, the term “NaCl” is in parentheses; it is unclear if this term is drawn to the claimed invention.

Regarding claim 23, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Regarding claim 23, the phrase "and the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "and the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim 18, The term “aromatic substance adjuvants” “whenever appropriate” and the meaning of the phrase “certain quantity” is unclear. Claim 18 is incomplete insofar as it fails to identify the variables “C1¹” and C1⁰. Claim 18 also states “the claimed range” which lacks antecedent basis.

Claim 29, the term “preferably” and “more preferably” in claim 29 is a relative term which renders the claim indefinite. The term " preferably" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is impossible to determine if the preferred embodiments are required Claim 18; no guidance is provided for determining the preferred embodiments.

Claims 18 and 29 recite the term "tenside" in parentheses, it is unclear if this term is drawn specifically to the claimed invention.

Claims 18 and 29 include the terms "suitable oxidation means." It is unclear what is meant by this term.

The term "saline chloride compound" is recited in claims 18 and 29. This term is unclear, as the term "saline", per se, is definite; "sodium chloride" is definite; "saline chloride" is confusing.

Claims 18-29 provide for the use of a disinfectant composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Berkowitz (WO 01/067,864).

Berkowitz discloses a topical compositions comprising an inorganic halide, oxidizer, sulfamic acid, inorganic phosphate, optional surfactant and pharmaceutical excipients.

The disclosed topical virucidal compositions is useful for preventing viral infection or cross infection especially in dental procedures. The disclosed formulations can be in ointments, emulsions and rigid foam forms. The oxidizer is preferably potassium persulfate or pyroxiphthalate. The non-reducing organic acid is succinic or preferably malic acid. The phosphate is disodium hydrogen- or potassium dihydrogen phosphate. The surfactant is selected from sodium dodecylbenzene sulfonate, lauryl ethyl sulfonate and polyethylene oxide/polypropylene oxide condensates. The formulation preferably contains an active viricide containing potassium persulfate triple salt, sodium chloride, disodium pyrophosphate and an anionic surfactant (see pages 2-3). The disclosed compositions meet the limitations of claimed invention since instant application merely requires the preparation of a biocidal composition. The composition's use in treating Candida is an intended use, and therefore has been given no patentable weight See MPEP §2106.

Lastly, claim in regards to claims 18, 20, and 28, the claimed pH reasonably appeared to be inherent. As stated in claim 18, the term "composition dissolved in a certain quantity of an aqueous solution will produce" appears before the pH values, and given that the production of such a pH is a result of a broadly claimed intended use, just about any normal disinfectant composition will have a pH falling within that range even without the term "certain quantity of aqueous solution", the intended use of the composition would certainly have a pH falling within the range. See MPEP §2106.

Claims 18-20, 23-27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Kross, et al (5100652).

Kross et al discloses a low concentration chlorous-acid generating compositions useful for oral hygiene (see abstract). Typical water-soluble chlorites include metal chlorites, such as alkali metal chlorites and alkaline earth metal chlorites (see column 4, lines 15-25). The oxidation means as disclosed are the vicinal hydroxy groups of the alpha-hydroxy carboxylic acid (see column 4, line 8). The compositions may be in the form of a mouthwash, toothpaste, chewing gum, or a solid, as in lozenges, or combined with fillers, as in a chewing gum (see column 4, lines 45-49). Dentifrices or toothpaste compositions, according to the disclosure, may also contain humectants, binders, and thickening agents (see column 4, lines 56-53, Example IV). The pH of the composition is generally less than about 7, typically from about 2.2 to about 7.0 (see column 3, lines 54-55). The compositions of the disclosed invention were tested to evaluate the antimicrobial effect on *C. albicans* (See examples IV and V).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 22 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kross, et al (5100652) in view of Watson, et al (5565145).

The teachings of Koss, et al have been discussed above. What is lacking in Koss et al is the teaching of a hydrogen peroxosulphate as an oxidation means in the claimed invention.

Watson, et al teaches Detergent formulators are faced with the task of devising products to remove a broad spectrum of soils and stains and for cleansing of prosthetics, such as denture in dentifrice compositions (see Examples XI and XII). Peroxygen bleaching agents can also be used. Suitable peroxygen bleaching compounds include sodium carbonate peroxyhydrate and equivalent "percarbonate" bleaches, sodium pyrophosphate peroxyhydrate, urea peroxyhydrate, and sodium peroxide. Persulfate bleach (e.g., OXONE manufactured commercially by DuPont, commercially available hydrogen peroxosulphate compound) can also be used (see column 14, lines 1-5.).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Koss, et al and Watson, et al as both Koss and Watson teach cleansing compositions for the purpose of oral hygiene and, for example, the cleansing of oral hygiene objects. A skilled artisan would have been motivated to use the teachings of Koss, combined with those of Watson to result in the claimed invention, with a reasonable expectation of success, as OXONE is a well known widely used as an oxidizing agent.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAHZAD SPIELER whose telephone number is (571)270-1557. The examiner can normally be reached on Weekly 8-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SS

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612